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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,576	03/19/2004	Fred H. Miller	027668-0108	7069

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	**PAPER NUMBER**
1609	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,576	MILLER, FRED H.	
	Examiner	Art Unit	
	Aradhana Sasan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58 and 60-136* is/are pending in the application.

4a) Of the above claim(s) *10-35, 54-105,119,120,123-126 and 129-136* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 36-53, 106-118, 121-122, and 127-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/31/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's response to Restriction Requirement filed on June 4, 2007.

Status of Application

Election/Restrictions

2. Applicant's election of Group I (claims 1-9, 36-53, 106-118), new claims 121-122, and 127-128, vitamin E as the elected species of ingredients to be put in the multi-compartment capsule, and "liquid" as the elected species in the reply filed on June 4, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 10-35, 54-105,119,120,123-126 and 129-136 are withdrawn from consideration.

4. Claims 1-9, 36-53, 106-118, 121-122, and 127-128 are being presented for examination.

Specification

5. The disclosure is objected to because of the following informalities:

Page 47, lines 23-24 should be "between a base 114 and a corresponding cap 112". Page 58, line 23, the dividing wall should be "626e". Page 63, line 25 should be "periphery of the cap 812". Page 66, line 28 should be "the filling material 940". Page 76, line 8 should be "mucopolysaccharide". Page 94, line 10 has the words "of the" repeated, it should be "immediate dissolution and release of the contents..."

Appropriate correction is required.

6. The use of several trademarks has been noted in this application: Medicaments like Tensilon®, Lopressor® etc. (Pages 111-130, 132, and 135). They should be written in all capital letters wherever they appear; or alternatively, they should be denoted with the registered trademark symbol, ®, and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. "S-adenosylmethione" (SAMe) should be "S-adenosylmethionine" (Page 78, lines 10-11, Page 79, line 5, Page 87, line 29, Page 88, line 20, Page 89, line 23, Page 162, line 23, claim 108, Page 162, line 27, claim 109, Page 164, line 2, claim 118).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 5-9, 36, 41-48, 50-53, 106-118, 121-122, and 127-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaharu et al. (JP 2000-239159).

The claimed invention is a multi-compartment capsule that provides active ingredients having diverse physical properties in a single dosage form.

Takaharu discloses a capsule preparation that "contains at least two kinds of medicinal ingredients which are separated into a plurality of ingredient phases ... and at

least one of these ingredient phases is in a liquid state" (Abstract). The capsules are filled with "two or more kinds of drug effect components" (Detailed Description, [0005]). Drugs "in the liquid condition, and a solid state" are encapsulated (Detailed Description, [0011]). The liquid ingredient in the capsule can be used "as long as it is the liquid which does not dissolve a capsule as a solvent which dissolves a drug effect component, ... it can be used regardless of whether it is hydrophilic or hydrophobic" (Detailed Description, [0014]). Examples of drugs such as water-soluble vitamins, fat-soluble vitamins, diphenhydramine hydrochloride are disclosed (Detailed Description, [0016, 0017]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with a plurality of ingredient phases, as suggested by Takaharu, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Takaharu teaches that "the therapeutic effectiveness of the capsule is high" (Detailed Description, [0026]). The incompatibility between the different drugs in the capsule is minimized. "Two or more sorts of drug effect components can be safely prescribed by one capsule" (Detailed Description, [0027]).

Regarding instant claims 1 and 36, the limitations of a first receiving chamber with an ingredient of a physical state being different (and having a different physical state) from an ingredient in the second receiving chamber would have been obvious to one skilled in the art over the capsule preparation with ingredients having different phases (solid and liquid) as suggested by Takaharu. The different chambers or

compartments of instant claim 1 would have been obvious over the capsule preparation of Takaharu because "the separated state is visibly recognizable from the outside of the capsule preparation..." (Abstract).

Regarding instant claims 5-8, and 45-48, the limitation of different physical states of the ingredients (solid, liquid, gas, and dispersion) would have been obvious to one skilled in the art over the plurality of ingredient phases in the capsule preparation taught by Takaharu. Takaharu teaches the encapsulation of drugs "in the liquid condition, and a solid state" (Detailed Description, [0011]).

Regarding the limitation of a third receiving chamber of instant claim 9, and 50-53, one skilled in the art would find it obvious to further include additional chambers with active ingredients having different physical states from active ingredients in previous chambers, given the capsule preparation with a plurality of ingredient phases of Takaharu.

Regarding instant claim 41-44, the limitation of an ingredient in the first receiving chamber being selected from a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral, would have been obvious to one skilled in the art over the active ingredients such as water-soluble vitamins, fat-soluble vitamins, diphenhydramine hydrochloride etc. as taught by Takaharu (Detailed Description, [0016, 0017]). One skilled in the art would select active ingredients (pharmaceutical drugs, nutraceutical ingredients, vitamins and minerals) for encapsulation according to the desired product profile and would modify the ingredients in the first and second chambers of the capsule depending on the desired combination of actives (be it

pharmaceutical in the first and second chambers or pharmaceutical in the first chamber and a nutraceutical or vitamin or mineral in the second chamber).

Regarding instant claims 106-118, 121-122, and 127-128, the combination of liquid vitamin E with solid active ingredients glucosamine/chondroitin, S-adenosylmethionine (SAMe), curcumin, Holy Basil, Zinc, Vitamin C, Fluoxetine, Rofecoxib, Diphenhydramine HCl, and Celecoxib along with the liquid omega-3 fatty acids DHA and EPA would have been obvious to one skilled in the art over the plurality of ingredient phases in capsules as taught by Takaharu. One skilled in the art would use solid active ingredients and liquid active ingredients (liquid Vitamin E and liquid omega-3 fatty acids DHA and EPA) in the multi-compartment capsule to enhance the therapeutic effectiveness.

10. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaharu et al. (JP 2000-239159) in view of Lebrun et al. (US 4,940,499).

The teaching of Takaharu is stated above.

Takaharu does not expressly teach sealing relationship between the cap and base of the capsule and reducing dead space within the first receiving chamber.

Lebrun teaches sealing capsules containing medicaments. "A suitable sealing liquid is applied to the capsules at the seams of their cap and body portions to be located between the overlapping side walls of the cap and body portions of the capsules..." (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with a plurality of ingredient phases, as suggested by Takaharu, and combine it with the sealing of the base and cap of the capsule, as suggested by Lebrun, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the sealing of the body and cap of the capsule "ensures positive retention of medicaments..." (Col. 4, lines 64-67).

11. Claims 3-4, 37, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaharu et al. (JP 2000-239159) in view of Lebrun et al. (US 4,940,499) and in further view of Story (US 5,738,871).

The teachings of Takaharu and Lebrun are stated above.

Takaharu and Lebrun do not expressly teach reducing the dead volume space within a chamber of the capsule.

Story teaches hard gelatin capsules containing a fat-soluble nutrient, a nonionic surfactant, a gelatin softening agent and optionally water (Col. 2, lines 47-50). "In cases of small quantities of active ... it is not actually necessary to have so much surfactant, but it is left in for convenience in filling and so as to not have so much dead space in the capsule" (Col. 6, lines 23-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a capsule with a plurality of ingredient phases, as suggested by Takaharu, combine it with the sealing of the base and cap of the capsule, as suggested by Lebrun, and further combine it with reducing the dead volume space

by using filling material such as surfactants, as suggested by Story, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the sealing of the body and cap of the capsule "ensures positive retention of medicaments..." (Col. 4, lines 64-67).

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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